



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,930	04/12/2004	Dario Neri	ELLIS-0002-P02-C01	3681
23599 7590 06/29/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER PORTNER, VIRGINIA ALLEN				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
06/29/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary

Application No.

10/821,930

Applicant(s)

NERI ET AL.

Examiner

GINNY PORTNER

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-26, 28-34 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-26, 28-34, 36-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 19-26,28-34,36-45 are pending; all claims are either new or amended claims.

Rejections Withdrawn

1. All prior art rejections are herein withdrawn in light of Applicant's amendment of the claims to recite a DNA deposit not disclosed or described in the prior art.
2. The obviousness type Double patenting over copending application 10/321, 558 has been obviated by filing of an effective terminal disclaimer.
3. The obviousness type double patenting over issued Patent 7,273,924 has been obviated by amending the claims to recite a species of antibody not described in the patent, a species that is not obvious over the instant pending claims; the obviousness type double patenting rejection is herein withdrawn.

Response to Amendment

1. The amendment filed March 10, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Specification and Claims: "DNA encoding antibody scFv L-19 has been deposited on September 25, 2008, in ATCC (Manassas, VA) and has accession number PTA-9529." The DNA deposited does not evidence original descriptive support in the instant Specification at the time of filing. Figure 6 provides the amino acid sequence for the L-19 antibody, but Applicant states that the sequence encoded by the deposited DNA encodes a different amino acid sequence from that disclosed in Figure 6, as originally filed.

Specification: The paragraph amendments at page 22 and 23 which change the positions for randomization from positions 32 and 50 to positions 33 and 50 do not evidence original descriptive support in the instant Specification, and is therefore New Matter.

2. The specific linker disclosed in the instant Specification (SEQ ID NO 31, 14 amino acids), is not the linker of the Deposited DNA which lacks the last two amino acids "TG". No linkers of 12 amino acids in length evidence original descriptive support in the instant Specification (see Figure 6, for amino acid sequence for the Linker has 14 amino acids).

3. Both the amended of Specification and the newly submitted claims that recite the ATCC deposit no. PTA-9529 which comprises a linker of 12 amino acids, and a different amino acid sequence for the VL chain, as well as a DNA coding sequence that did not evidence original descriptive support at the time of filing of the instant Specification is considered to be New Matter.

Claim Rejections - 35 USC § 112

4. Claims 19-26,28-34, 36-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claims 19-26, 28-34 all claim an antibody or methods of administering an antibody that is encoded by a DNA coding sequence that did not evidence original descriptive support at the time of filing of the instant Specification. Upon consideration of Example 2, the examiner found the example to generate 4×18^8 clones, of which 25 % were positive. The amino acid sequence for L19 is shown in original Figure 6. No other sequences for L19 have been described or

disclosed. The Deposited DNA purports to encode an amino acid sequence other than that described in the instant Specification for L19, for both the linker and the VL chain; the recitation of this coding DNA based upon a Deposit that was not set forth in the original Specification and is described as encoding amino acid sequences other than what the instant Specification provides original descriptive support, introduces New Matter into the amended claims and Specification.

6. Claims 36-45 all claim an antibody that comprises a linker encoded by DNA of the Deposit ATCC No. PTA-9529. The linker of the newly submitted claims does not evidence original support in the instant Specification which discloses a linker of 14 amino acids, SEQ ID No 31, and not a linker lacking the last two amino acids "TG". All of the claims recite a species of linker that does not evidence original descriptive support in the instant Specification or the original claims. Claims 36-45 recite New Matter.

7. Claim 28 has been amended to recite a conjugate that comprises a molecule that is both a "photosensitizer and a molecule which is a radionuclide", but original descriptive support such a molecule could not be found in the instant Specification. Tin chlorin e6 is a photosensitizer, but not a radionuclide and a Beta emitter is a radionuclide, but is not a photosensitizer. Therefore the amendment of claim 28 introduces a new subgenus of species of conjugate that does not evidence original descriptive support in the instant Specification.

Claim Objections

8. Claim 24 is objected to because of the following informalities: Claim 24 recites the term chlorine, but should be chlorin. Appropriate correction is required.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
December 3, 2008

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645